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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/640,081	08/13/2003	James M. Minor	10030208-1	7915

22878 7590 10/12/2006

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EXAMINER	
SHIBUYA, MARK LANCE	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/640,081	MINOR, JAMES M.	
	Examiner	Art Unit	
	Mark L. Shibuya	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) *24-29 and 35-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23 and 30-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/13/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-41 are pending. Claims 24-29 and 35-41 are withdrawn. Claims 1-23 and 30-34 are examined.

Election/Restrictions

2. Applicant's election with traverse of Group I, claims 1-23 in the reply filed on 7/17/2006, is acknowledged. The traversal is on the ground(s) that the method of Group I can be used to determine to determining phase relationships as in the method of Group III, (claims 30-34). This is found persuasive, the claims of the invention of Group III are rejoined to Group I, and the requirement for restriction between these two groups is withdrawn hereby. Applicant has not meaningfully traversed the restriction of the elected invention from Group V, drawn to a computer readable medium carrying instructions for screening a combination of treatments. Applicant's traversal with regard to Group V is not found persuasive also because the instructions of the computer readable medium may be performed by hand.

The requirement is still deemed proper and is therefore made FINAL.

3. Applicant's election with traverse of the species in the reply filed on 7/17/2006 is acknowledged. The traversal is on the ground(s) that the various species are member

of Markush style claims. This is found persuasive and the requirement for election of species is withdrawn.

4. Claims 24-29 and 35-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/17/2006.

Priority

5. This application was filed 8/13/2003.

Information Disclosure Statement

6. The information disclosure statement (IDS) submitted on 8/13/2003 has been considered by the examiner.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-23 and 30-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is for lack of written description.

The claims are drawn to a method of screening a combination of treatments to target a disease process comprising providing differential expression levels of diseased tissue samples.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

One of skill in the art cannot envision the detailed sequences of differential expression levels for the genus of disease processes. The specification does not provide any example, working or otherwise of differential gene sequence expression indicative of the genus of disease processes. The genus of disease processes includes many diseases known to or suspected of having a genetic association; however the identification of the genus of genes whose expression levels correlate with a disease and whose change would indicate treatment efficacy has not been accomplished for the wide genus of disease processes. The specification does not disclose a representative number of species of differential expression levels of diseased processes such that one

of skill in the art would envision that applicant had possession of the full scope of the claimed invention. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-4, 6-22, 30-33, are rejected under 35 U.S.C. 103(a) as being unpatentable over Muraca, US Publication 20030049701 A1, in view of Glinskii, US Publication 20040053317 A1.

The claims are drawn to a method for screening a combination of treatments to specifically target a disease process comprising:

-providing differential expression levels of disease tissue samples as features of microarrays;

-treating the disease tissue samples

-generating a phenotypic signature representing the treatment response

-repeating the aforementioned steps

-performing a clustering operation based on the phenotypic/genotypic signatures;

-selecting treatments; and variations thereof.

Muraca, US Publication 20030049701 A1, throughout the publication, and at para [0006], [0014]-[0017], [0023], [0205], teach oncology microarrays upon which samples from patients treated with chemotherapy, etc. may be assayed. Muraca, at para [0035], teach guiding treatment based on the comparative levels of one or more cell-growth related polypeptides.

Muraca at para [0044], [0062]-[0065] disclose a computer–assessable file regarding a collection of information regarding a tissue sample, reading on remote transmission of data.

Muraca does not disclose performing a clustering operation based on phenotypic or genotypic signatures.

Glinskii, US Publication 20040053317 A1, throughout the publication, and e.g., at para [0407], teaches the use of Affymetrix arrays for assaying gene expression, and at, e.g., para [0413]-0421], [0426], teaches the use of clustering methods to analyze gene expression profiles. Glinskii, at para [0413], teaches that clinically relevant genetic signatures can be found by searching for clusters of co-regulated genes.

It would have been *prima facie* obvious, at the time the invention was made, for one of ordinary skill in the art to have made and used method for screening a combination of treatments to specifically target a disease process comprising performing a clustering operation based on the phenotypic/genotypic signatures.

In regard to the use of density center analysis, such use would be an inherent feature of cluster analysis, as taught by Glinskii.

In regard to two-color or two channel microarray processes, such uses would be obvious over the Affymetrix array techniques taught by Glinskii.

In regard to the various efficacies and toxicities in screening combinations of treatments, such considerations would be obvious in view of the clinical setting taught by Muraca.

One of ordinary skill in the art would have been motivated to make and use methods comprising performing a clustering operation based on the phenotypic/genotypic signatures because Glinskii teaches that clinically relevant genetic signatures can be found by searching for clusters of co-regulated genes

One of ordinary skill in the art would have had a reasonable expectation of success in using clustering methods for selecting treatments, because Glinskii at, e.g., para [0426], teaches identifying human prostate tumor gene clusters using clustering analysis.

Conclusion

11. Claims 1-23 and 30-34 are rejected.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Shibuya whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark L. Shibuya
Examiner
Art Unit 1639